

Applicants: Walter P. Carney, et al.
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REMARKS

Claims 16-27 are pending. Claims 16-24 are allowed. Claims 25-27 are under examination. No claim has been added, canceled or amended herein. Accordingly, claims 16-27 are still pending and claims 25-27 are still under examination.

In view of the arguments set forth below, applicants maintain that the Examiner's rejections made in the June 6, 2003 Final Office Action have been overcome, and respectfully request that the Examiner reconsider and withdraw same.

The Claimed Invention

This invention relates to the detection and/or quantification of the extracellular domain of the human neu gene product in the biological fluids of humans using monoclonal antibodies which are capable of binding to this protein. Specifically, this invention provides a monoclonal antibody which is capable of binding to the extracellular domain of the human neu gene product, said product being detectable in a biological fluid by its immunoreactivity with a monoclonal antibody produced by the hybridoma cell line OD-3, NB-3 or TA-1, or with an immunoreactive fragment thereof.

Rejections Under 35 U.S.C. §102(e)

The Examiner rejected claims 25-27 under 35 U.S.C. §102(e) as allegedly anticipated by Ring, et al. (U.S. Patent No. 6,054,561). The Examiner also rejected claims 25-27 under 35 U.S.C. §102(e) as allegedly anticipated by Hudziak, et al. (U.S. Patent Nos. 5,720,937 and 5,772,997).

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In response to the Examiner's rejections, applicants respectfully traverse.

To anticipate the invention of claims 25-27, each of the Ring and Hudziak patents would have to teach each and every element thereof.

None of these references does this.

Ring teaches a breast cancer-specific antibody designated 520C9 that binds to an approximately 200 kDa protein identified as "c-erbB-2." Ring does not teach a monoclonal antibody which is capable of binding to the extracellular domain of the human neu gene product which, as stated on page 6 of the specification, has a molecular weight of about 97 to 115 kDa. Furthermore, Ring does not teach that the product is *detectable in a biological fluid* by its immunoreactivity with a monoclonal antibody produced by the hybridoma cell line OD-3, NB-3 or TA-1, or with an immunoreactive fragment thereof.

Also, applicants respectfully disagree with the Examiner's assertion that the antigens disclosed in the Ring patent, i.e., those ranging from 40-200 kDa, read on applicants' range. The only antigen that falls within the range stated on page 6 of the specification, i.e., about 97 to 115 kDa, is a *diffuse band* with an approximate molecular weight of 100 kDa which is recognized by the 113F1 antibody. There is no teaching in Ring, et al. that the 113F1 antibody binds to the extracellular domain of the human neu gene product, nor even the "200 kDa protein identified as c-erbB-2" disclosed in Ring, et al., for that matter. As stated at column 27, lines 22-24 of Ring, et al., the 100 kDa band is one of a number of bands which "are suspected to be one or more

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glycoproteins bearing the same or similar carbohydrate."

Each of the Hudziak patents teaches a monoclonal antibody that specifically binds to the extracellular domain of the HER2 receptor, and an assay for detecting tumors by determining the extent of binding of the antibody to tumor cells.

Like Ring, the Hudziak patents do not teach that the product is detectable in a biological fluid by its immunoreactivity with a monoclonal antibody produced by the hybridoma cell line OD-3, NB-3 or TA-1, or with an immunoreactive fragment thereof. Also like Ring, the Hudziak patents do not teach that the product is detectable in a biological fluid at all. The Hudziak patents therefore fail to teach each and every element of the rejected claims.

Therefore, the Ring and Hudziak patents all fail to teach each and every element of claims 25-27, and therefore, claims 25-27 are novel over each of these references.

In view of the above remarks, applicants maintain that claims 25-27 satisfy the requirements of 35 U.S.C. §102(e).

Summary

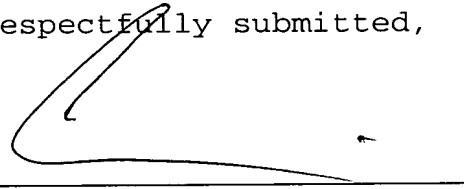
In view of the remarks made herein, applicants maintain that all of the claims pending in this application are now in condition for allowance. Accordingly, allowance is respectfully requested.

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If a telephone interview would be of assistance in advancing the prosecution of the subject application, applicants' undersigned attorneys invite the Examiner to telephone them at the number provided below.

No fee, other than the enclosed \$110.00 extension fee, is deemed necessary in connection with the filing of this Communication. However, if any additional fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,



I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:

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10/6/03
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